IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THERESA DRUMHELLER	:	**CIVIL ACTION**
	:	
v.	:	**NO. 20-6535**
	:	
JOHNSON & JOHNSON, *et al.*	:	

MEMORANDUM

KEARNEY, J. **May 10, 2021**

A Montgomery County surgeon implanted Ethicon PROLENE* pelvic mesh in Theresa Drumheller on February 27, 2009 and on April 16, 2010.[1] Ethicon, Inc. designed, developed, marketed, tested, distributed and sold the pelvic floor repair products implanted in Ms. Drumheller.[2] Ms. Drumheller developed complications, including worsening urinary incontinence, intrinsic sphincter deficiency, pelvic pain, dyspareunia, stress, and anxiety.[3] She now sues Ethicon and Johnson & Johnson under a variety of negligence, strict liability, breach of warranty, fraud, and unjust enrichment claims. She does not plead when these complications began after her last surgery in 2010. She instead pleads facts largely derived from public records relating to Ethicon's product. Ethicon now moves to dismiss her first amended Complaint. While we can fairly question the timeliness of her negligence claims under a tolling theory, we will allow the parties to explore those issues in discovery, and then address Ms. Drumheller's three surviving claims for negligence in design and in failure to warn, and negligent infliction of emotional distress. We dismiss her remaining negligence, strict liability, warranty, fraud, misrepresentation, and unjust enrichment claims.

I. Ms. Drumheller's allegations relating to the pelvic mesh product.

Ms. Drumheller devotes almost all her first amended Complaint to retelling a story of Ethicon's pelvic mesh products presumably on background without identifying a nexus to her or her surgeon other than her surgeon's implanting the pelvic mesh over ten years ago. She further alleges worsening urinary incontinence, intrinsic sphincter deficiency, pelvic pain, dyspareunia, stress, and anxiety. But she does not disclose when she began suffering these complications or treatments for them.

History of Ethicon's pelvic mesh products.

In the 1970s, gynecologists began using surgical mesh products designed for abdominal hernia repair to surgically repair prolapsed organs.[4] Twenty years later, gynecologists began using the surgical mesh for the treatment of pelvic organ prolapse and stress urinary incontinence.[5] Ms. Drumheller alleges manufacturers of the mesh product, including Ethicon, began to modify the mesh used in hernia repair to be used as products specifically intended to correct pelvic organ prolapse and stress urinary incontinence.[6] In 1996, the Food and Drug Administration cleared the first pelvic mesh products for use in the treatment of stress urinary incontinence, including the products manufactured, marketed, and distributed by Ethicon.[7]

Surgical mesh, including mesh used in pelvic mesh products, is a medical device generally used to repair weakened or damaged tissue.[8] It is made from porous, absorbable or non-absorbable synthetic material or absorbable biologic material.[9] In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.[10] Most pelvic mesh products are made up of non-absorbable, synthetic, monofilament polypropylene mesh and/or collagen.[11]

Ms. Drumheller claims these pelvic mesh products create a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when implanted in the female body according to the manufacturers' instructions.[12] Ms. Drumheller alleges the pelvic mesh products manufactured by Ethicon contain polypropylene mesh.[13] She claims scientific evidence shows this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Ethicon's pelvic mesh products.[14] The immune response allegedly promotes degradation of the polypropylene mesh and the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.[15] Ms. Drumheller claims the polypropylene mesh causes a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Ethicon's pelvic mesh products.[16]

She also alleges pelvic mesh products contain collagen, which causes hyper-inflammatory responses including chronic pain and fibrotic reaction.[17] Ms. Drumheller contends Ethicon's collagen-containing products disintegrate after implantation into the pelvis, causing adverse tissue reactions and infections.[18]

Ms. Drumheller further alleges "the use of laser-cut or mechanical cut polypropylene mesh in [Ethicon's] manufacturing process for the [prolene mesh] contributed to the sharp edges of the device," and "the mechanical cut . . . mesh will curl, rope, degrade, exhibit particle loss, and cause associated injuries."[19] "Likewise, laser cut mesh . . . leads to mesh erosions and associated injuries."[20]

Warnings regarding Ethicon's pelvic mesh products.

Ms. Drumheller alleges Ethicon developed and sold the pelvic mesh after representations to the FDA of "Substantial Equivalence" under the Food, Drug and Cosmetic Act.[21] This

clearance does not require the applicant to prove safety or efficacy and the FDA conducted no formal review of the safety and efficacy of Ethicon's pelvic mesh products.[22] Because of a series of warnings from the FDA and other medical professionals and advocates, she claims Ethicon knew or should have known the products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives which do not involve the same risks.[23]

Ms. Drumheller claims the FDA issued a Public Health Notification in 2008, describing over one thousand complaints, or "adverse events," reported over a three-year period relating to pelvic mesh products.[24] Although the FDA notice did not identify the manufacturers by name, Ms. Drumheller alleges the FDA's database identifies Ethicon as a manufacturer of the pelvic mesh products in the notification.[25]

The FDA issued a new warning three years later about serious complications associated with pelvic mesh products, including the Ethicon products.[26] The FDA warned, "serious complications associated with surgical mesh for transvaginal repair of [pelvic organ prolapse] are not rare."[27] Ms. Drumheller claims the FDA warning also stated "it is not clear that transvaginal [pelvic organ prolapse] repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."[28]

The FDA then released another publication, referred to as the "White Paper" by Ms. Drumheller, recognizing published and peer-reviewed literature which she claims demonstrates "[p]atients who undergo [pelvic organ prolapse] repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."[29] The White Paper represented "[pelvic mesh] products are associated with serious

adverse events," and the FDA "identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."[30]

Ms. Drumheller further alleges consumer advocacy group Public Citizen submitted a petition to the FDA in August 2011, seeking to ban the use of pelvic mesh products in pelvic repair procedures.[31] Public Citizen warned pelvic mesh products should be recalled because they offer no significant benefits, and expose patients to serious risks and the potential for permanent life-altering harm.[32]

Ms. Drumheller alleges the American College of Obstetricians and Gynecologists and the American Urogynecologic Society identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with the mesh.[33] They jointly opined "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh replacement may justify the risk."[34]

The FDA in April 2019 ordered all transvaginal [pelvic organ prolapse] device manufacturers, including Ethicon, to stop selling and distributing these products immediately.[35] Ms. Drumheller claims the FDA found there had not been sufficient evidence to assure the probable benefits of the products outweighed their probable risks, and concluded the products do not have a reasonable assurance of safety and effectiveness.[36]

Marketing of pelvic mesh

Ms. Drumheller claims Ethicon's pelvic mesh products are "promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse or to support the urethra to treat urinary incontinence."[37] Ethicon sells pelvic mesh "kits," which can include the

surgical mesh and tissue fixation anchors and insertion tools.[38] The products manufactured by Ethicon are considered Class II medical devices.[39]

Ms. Drumheller also claims the products are defective because Ethicon failed to adequately warn or instruct her or her healthcare provider of known risks, including the products' propensity to contract, retract, and/or shrink inside the body; the products' inelasticity preventing proper mating with the pelvic floor and vaginal region; the frequency and manner of transvaginal mesh erosion or extrusion; and the risks and hazards associated with the implantation of the products.[40]

Ms. Drumheller alleges Ethicon has and continues to market the pelvic mesh products to the medical community and directly to patients as safe, effective, and reliable medical devices.[41] Ms. Drumheller also claims Ethicon marketed and sold the pelvic mesh products to the medical community and directly to patients through "carefully planned, multifaceted marketing campaigns and strategies."[42] Some of these techniques Ms. Drumheller refers to include aggressive marketing to health care providers at medical conferences, hospitals, private offices, and the provision of valuable cash and non-cash benefits to healthcare providers.[43] Ethicon also used documents, patient brochures, and websites offering "exaggerated and misleading expectations as to the safety and utility of the pelvic mesh products" and engaged in "direct-to-consumer marketing specifically designed to drive consumers to seek out the [pelvic mesh] products for implantation into their bodies."[44]

II. Analysis

Ms. Drumheller sued Ethicon alleging: negligence; design defect; manufacturing defect; failure to warn; common law fraud; breach of express warranty; breach of implied warranty; constructive fraud; negligent misrepresentation; negligent infliction of emotional distress; gross negligence; fraudulent concealment; unjust enrichment; and punitive damages.

Ethicon moves to dismiss the entire complaint as an impermissible "shotgun pleading."[45] It argues Ms. Drumheller's strategy largely ignores disclosing her nexus to harm and instead recites general facts about pelvic mesh. It argues she provides insufficient detail about Ms. Drumheller's specific situation to put Ethicon on notice of the claims against it and allow Ethicon to assess potential affirmative defenses, including potential statute of limitations defenses. Ethicon alternatively argues we should dismiss: (1) the negligence and gross negligence claims because Ms. Drumheller failed to plead a design defect, a failure to warn, or a manufacturing defect; (2) the strict liability claims because Pennsylvania law does not allow such claims for prescription medical devices; (3) the breach of warranty claims as time-barred, inadequately pled, and partially foreclosed by Pennsylvania's limitations on the types of claims available for prescription medical devices; (4) the fraud and misrepresentation claims because Pennsylvania law precludes fraud and misrepresentation claims involving prescription medical devices and, even if it did not, Ms. Drumheller's claims do not meet Rule 9's heightened pleading standard; (5) the negligent infliction of emotional distress claim because Ms. Drumheller does not adequately allege emotional harm; (6) the unjust enrichment claim as inadequately pled; and (7) the punitive damages claim as derivative of the underlying claims which should be dismissed.

Ms. Drumheller responds she has not filed an impermissible "shotgun" pleading, her claims are adequately pled, and Pennsylvania law does not foreclose any of her claims or categories of claims. But Ms. Drumheller does not oppose our dismissal of her gross negligence claim because she concedes Pennsylvania law does not recognize gross negligence as a standalone claim.

We first find Ms. Drumheller's first amended Complaint does not constitute a shotgun pleading in the classic sense. But her strategy raises fair questions in discovery regarding her injuries, discovery, and treatment. We then assess the merits of Ms. Drumheller's individual claims. We find Ms. Drumheller states a claim for negligent design and negligent failure to warn, but does not state a claim for negligent manufacturing. We find Pennsylvania law bars Ms. Drumheller's strict liability design defect and failure to warn claims. While we find her strict liability manufacturing defect claim available under Pennsylvania law, we find she fails to plead a manufacturing defect.

We dismiss Ms. Drumheller's breach of implied warranty claim as time-barred. While we decline to find her breach of express warranty claim time-barred, we find Ms. Drumheller's breach of express warranty claim inadequately pled. We find Pennsylvania law bars Ms. Drumheller's fraud claims. We find Ms. Drumheller adequately pleads negligent infliction of emotional distress. We dismiss Ms. Drumheller's claim for gross negligence with her consent. We dismiss Ms. Drumheller's unjust enrichment claims as inadequately pled. And we dismiss Ms. Drumheller's standalone claim for "punitive damages" because punitive damages are a remedy, not a claim. The parties may proceed into discovery on her negligent design, negligent failure to warn, and negligent infliction of emotional distress claims.

A. Ms. Drumheller's first amended Complaint is not a "shotgun pleading."

Ethicon argues Ms. Drumheller's first amended Complaint is an impermissible "shotgun pleading" with general allegations regarding pelvic mesh and few facts regarding her specific situation. Ms. Drumheller does not allege: the specific pelvic mesh devices implanted in her; the medical condition for which she received the pelvic mesh implantation; the dates her injuries manifested; or details regarding corrective treatment. The lack of details specific to Ms. Drumheller, Ethicon argues, makes it impossible to "ascertain the viability of rudimentary defenses, such as whether her claims are time barred."[46] Ms. Drumheller argues the first amended Complaint is not a "shotgun pleading" because it alleges sufficient detail to put Ethicon on notice of the claims against it. She also argues Ethicon fails to cite authority suggesting a plaintiff must plead facts sufficient to allow the defendant to assess its statute of limitations defense. We agree with Ms. Drumheller.

There are four different types of shotgun pleadings: "(1) 'a complaint containing multiple counts where each count adopts the allegations of all preceding counts'; (2) a complaint that is 'replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action'; (3) a complaint that does not 'separat[e] into a different count each cause of action or claim for relief'; and (4) a complaint that 'assert[s] multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against."[47] "The 'unifying characteristic' of these four types of shotgun pleadings 'is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests."[48]

Ms. Drumheller's allegations, albeit largely focused on Ethicon on a macro level rather than the discovery and treatment of specific harm, does not fall into any of these four categories. She specifies the allegations tied to each count. She alleges many facts which, although general, tend to support her allegations Ethicon designed, manufactured, marketed, and sold a dangerously defective product which caused her injuries. She separates her claims into fourteen causes of action. She names only two defendants, and she alleges the role of each defendant.

Ethicon's argument Ms. Drumheller's complaint is a shotgun pleading because she fails to plead sufficient facts to show the timeliness of her complaint squarely contradicts the law of this Circuit. Our Court of Appeals has repeatedly held "because a statute of limitations is an affirmative defense, 'the burden of establishing its applicability to a particular claim rests with the defendant.'"[49] "[A] plaintiff is not required to negate an affirmative defense in his complaint."[50] "Indeed, requiring a plaintiff to plead compliance with the statute of limitations would effectively ensure that a timeliness issue would always appear on the face of a complaint, thereby shifting the burden to the plaintiff to negate the applicability of the affirmative defense."[51]

Ms. Drumheller pleads several conclusory allegations as to why we should toll the statute of limitations since she filed suit on December 30, 2020, over ten years after the surgeon implanted the pelvic mesh device. We are hesitant to allow Ms. Drumheller to plead tolling statute of limitations without pleading when she knew or should have known of her injuries. Ethicon has not moved on statute of limitations grounds except on the warranty claim. We expect it knows of our required deference to the allegations. But initial discovery may allow Ethicon an ability to obtain summary judgment on this defense. We also today set our initial pretrial conference. We expect to consider whether an initial expedited period of discovery beginning

today should focus on responses to targeted Rule 33 and 34 requests, limited third party document subpoenas, and limited depositions on whether Ms. Drumheller's remaining three claims are timely filed and the initial scope of her injury to support the barest bones of allegations sufficient to satisfy Rule 8.

B. Ms. Drumheller states a claim for negligence under a design defect theory and a failure to warn theory, but not under a manufacturing defect theory.[52]

Ms. Drumheller alleges Ethicon negligently designed, researched, manufactured, marketed, labeled, packaged, supplied, distributed, and sold the Prolene pelvic mesh products, causing her injuries. Ethicon argues Ms. Drumheller fails to adequately plead a design defect or a manufacturing defect, and the learned intermediary doctrine bars her failure to warn claims. We find Ms. Drumheller states a claim for negligent design, but we agree with Ethicon she fails to plead a manufacturing defect. We further find the learned intermediary doctrine does not bar her failure to warn claims.

i. Ms. Drumheller states a claim for negligent design.

Ethicon argues Ms. Drumheller fails to state a claim for negligent design because "she does not even identify the specific devices" implanted in her and "she pleads no facts whatsoever that would plausibly link her injuries to the alleged defect(s)."[53] Ms. Drumheller argues her allegations are sufficient and clarifies the device implanted in her was the PROLENE* device. Ethicon replies the specific mesh product PROLENE* is not intended to treat stress urinary incontinence, and Ethicon cannot be held liable for Ms. Drumheller's off label use. We find Ms. Drumheller's allegations sufficient at this early stage to state a negligent design claim.

Ms. Drumheller alleges surgeons implanted "an Ethicon Prolene pelvic mesh product" and she "subsequently developed complications arising from the implant of the [Ethicon pelvic mesh] product, including mesh implant complications necessitating removal, mesh migration,

worsening urinary incontinence, intrinsic sphincter deficiency, pelvic pain, dyspareunia, and stress and anxiety."[54] She alleges pelvic mesh products are made of polypropylene, which she alleges to be "biologically incompatible with human tissue" and to cause "a severe foreign body reaction and chronic inflammatory response."[55] She alleges "[t]his 'host defense response' by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain."[56] She also alleges the pelvic mesh products contain collagen, which causes hyperinflammatory responses, adverse tissue reactions, and infections.[57]

Her allegations place Ethicon on notice of the negligent design claim. Ms. Drumheller alleges the specific injuries she suffered – worsening urinary incontinence, intrinsic sphincter deficiency, pelvic pain, dyspareunia – and she identifies how the specific design characteristics of the products – the use of polypropylene and collagen – contributed to these injuries.

Ethicon further argues it designed Prolene pelvic mesh for hernia repair, not for treatment of stress urinary incontinence, and thus Ethicon cannot be held liable for Ms. Drumheller's off-label use. Ethicon's instructions advise, "[t]his mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired result."[58] Even assuming we could consider these instructions as incorporated by reference into the complaint – a fact of which we are not convinced – these instructions would be insufficient for us to find the treatment of stress urinary incontinence to be an "off label use" because we have nothing before us defining the scope of the phrase "other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical

result." The treatment of Ms. Drumheller's condition as an "off label use" is a matter for discovery.

ii. Ms. Drumheller fails to state a claim for negligent manufacturing.

Ethicon argues Ms. Drumheller fails to plead a negligent manufacturing defect because she fails to plead how the Prolene mesh product deviated from its intended design. Ms. Drumheller argues we should allow her manufacturing defect to proceed to discovery because, as many courts have recognized, it is "difficult for [a plaintiff] to pinpoint a specific source of defect" before discovery.[59] As the gravamen of Ms. Drumheller's complaint is defect in the design of pelvic mesh, we find she fails to plead a manufacturing defect.

To plead a negligent manufacturing claim, Ms. Drumheller must allege "(1) the manufacturer owed a duty to [her], (2) the duty was breached and (3) such a breach was the proximate cause of plaintiff's injuries."[60] To allege breach, Ms. Drumheller must plead facts showing Ethicon "failed to exercise due care in manufacturing or supplying the product."[61] "Generally, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line."[62] "The 'manufacturing defect' theory posits that 'a suitable design is in place, but that the manufacturing process has in some way deviated from that design.'"[63]

Ms. Drumheller fails to state a manufacturing defect claim. The gravamen of Ms. Drumheller's complaint is Prolene pelvic mesh products are dangerous as designed. In support of her manufacturing defect claim, Ms. Drumheller alleges defect "due to the use of non-medical grade material and inadequate specifications" in the manufacturing of her pelvic mesh device.[64] With regard to the alleged non-medical grade materials, Ms. Drumheller specifies, "Defendants'

[mesh] device that was implanted in Plaintiff deviated from its intended design by utilizing a polypropylene mesh that degrades, contracts, shrinks, [etc.]."[65] In alleging the specifications were "inadequate" and the product used the defective material "polypropylene," Ms. Drumheller is really alleging a design defect, not a manufacturing defect. Given the product is called "prolene mesh," it is not plausible the design of the product called for a different material and the manufacturer deviated from this design by using polypropylene. And if, as Ms. Drumheller alleges, the specifications were "inadequate," then the specifications were unsuitable as designed.

Ms. Drumheller also alleges the way Ethicon cut the polypropylene mesh either mechanically or by laser created problems upon implant.[66] This allegation again goes to the design of the product. A manufacturing defect occurs when the product deviates from the "manufacturer's intended result or from other ostensibly identical units of the same product line."[67] Ms. Drumheller does not allege the laser or mechanical cut was unique to the specific product implanted in her. She instead alleges pelvic mesh products are generally made this way, negatively affecting her and all other patients implanted with pelvic mesh. As Ms. Drumheller fails to allege facts showing a deviation from a suitable design, she fails to state a claim for negligent manufacturing.

iii. Ms. Drumheller states a claim for negligent failure-to-warn.

Ethicon argues Ms. Drumheller does not allege how the pelvic mesh products' warnings were inaccurate because she does not address what was contained in the products' warnings, and, in light of the learned intermediary doctrine, she fails to plead proximate cause. Ms. Drumheller argues the learned intermediary doctrine does not bar her claims because she pleads Ethicon

failed to warn her implanting physician of the product's dangers. We agree with Ms. Drumheller at this stage.

"In cases involving the failure to warn of risks associated with prescription drugs [and devices], Pennsylvania applies the learned intermediary doctrine."[68] Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the [device] likely to be dangerous."[69] The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of the characteristics device and the patient's medical history.[70] It is also the duty of the prescribing physician to advise the patient of dangers or side effects associated with the use of the device.[71]

"Proximate cause is an essential element in a failure to warn case."[72] "A proximate, or legal cause, is defined as a substantial contributing factor in bringing about the harm in question."[73] Ms. Drumheller can show proximate cause "by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided."[74]

In *Runner v. C.R. Bard*, a surgical mesh case, Judge Dalzell denied the mesh manufacturer's motion to dismiss the negligent failure-to-warn claim notwithstanding the learned intermediary doctrine.[75] He explained, "the plaintiff has sufficiently pled the defendants failed to exercise reasonable care in informing his healthcare providers of any alleged defects thus depriving him of the benefit of his prescribing physician's advice as to those alleged dangers."[76] He continued, "[w]hether the defendants exercised reasonable care in informing [Plaintiff's] doctor, and whether such a warning would have moved his physician to alter the plaintiff's care are matters of fact that cannot be resolved at this early stage of litigation."[77]

Ms. Drumheller pleads Ethicon "did not provide sufficient or adequate warnings to . . . [Ms. Drumheller's] medical providers, the medical community, [and] the FDA."[78] Specifically, she alleges Ethicon knew their products had a propensity to "degrade[], contract[], shrink[], fray[], cord[], migrate[], stiffen[], lose[] pore size with tension and/or otherwise deform[]", but they failed to inform medical professionals of these characteristics.[79] We agree with Judge Dalzell these allegations are sufficient at this early stage of litigation to state a claim for negligent failure to warn.

C. Pennsylvania law forecloses Ms. Drumheller's strict liability design defect and failure-to-warn claims but does not foreclose her strict liability manufacturing defect claim.

Ms. Drumheller asserts three types of strict liability claims: (1) manufacturing defect; (2) design defect; and (3) failure to warn. Ethicon moves to dismiss all of these claims, arguing Pennsylvania law does not allow strict liability claims arising from the use of prescription medical devices, like pelvic mesh. Ms. Drumheller argues Pennsylvania's limitation on strict liability claims extends only to prescription medical drugs, but does not cover prescription medical devices. If we find Pennsylvania's limitation extends to prescription medical devices, Ms. Drumheller argues we should find the limitation applies to only design defects and failure to warn defects, but not manufacturing defects.

We predict the Pennsylvania Supreme Court would bar strict liability for design defects and failure-to-warn defects for prescription medical devices, but would not bar strict liability for manufacturing defects. But while we find Pennsylvania law does not foreclose Ms. Drumheller's strict liability manufacturing defect claim, we find Ms. Drumheller fails to plead a manufacturing defect.

i. Pennsylvania law does not recognize strict liability claims arising from design defects or failure to-warn for prescription devices.

"Pennsylvania has adopted the strict liability formulation set out in Section 402A of the Restatement (Second) of Torts."[80] Under Pennsylvania law, "a plaintiff may recover under a theory of strict liability if his or her injury was caused by a product in a defective condition unreasonably dangerous to the user or the consumer."[81] "A plaintiff may establish a 'defective condition,' and thus assert a strict liability claim, by showing that the product suffered from a design defect, failure-to-warn defect, or manufacturing defect."[82]

But Pennsylvania law also recognizes "situations where strict liability is unavailable as an avenue of relief for plaintiffs alleging harm caused by a product."[83] Comment k to Section 402A of the Second Restatement provides, "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."[84] It explains this is "especially common in the field of drugs" and vaccines.[85] Comment k uses the rabies vaccine as an example.[86] It explains the rabies vaccine "not uncommonly leads to very serious and damaging consequences when it is injected," but "[s]ince the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve."[87] It explains, "[s]uch a product, properly prepared, and unaccompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."[88] It continues, "[t]he same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician."[89] The comment concludes, "[t]he seller of such products, again with the qualification that they are properly prepared and marketed, and proper warnings is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the

public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."[90]

In *Hahn v. Richter*, the Pennsylvania Supreme Court explained held comment k "denies application of strict liability to products such as prescription drugs which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings."[91] Looking to comment j of the Section 402A of the Restatement, the court clarified, "'directions or warning,' provides that a seller must warn of risks not generally known and recognized, of which he *has or reasonably should have knowledge*, and, further, that it can be assumed that where warnings are given they will be read and heeded."[92] The court held "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability."[93] The Pennsylvania Superior Court later explained in *Lance v. Wyeth*, "a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs."[94]

Following *Hahn* and *Lance*, courts generally agree strict liability claims for failure-to-warn and design defects are not available in cases involving prescription drugs under Pennsylvania law. But open questions remain regarding whether comment k and *Hahn* extend to (1) strict liability claims involving prescription medical *devices*; and (2) strict liability claims based on manufacturing defects. We discuss these questions in turn.

ii. We predict the Pennsylvania Supreme Court would extend comment k and *Hahn* to preclude strict liability for design and failure to warn defects in prescription medical devices.

We predict the Pennsylvania Supreme Court would preclude strict liability for design defect and failure-to-warn claims involving prescription medical devices under comment k and *Hahn.*

In *Creazzo v. Medtronic*, the Pennsylvania Superior Court extended *Hahn* and comment k to preclude strict liability for design of medical devices, finding "no reason why the same rational [sic] applicable to prescription drugs may not be applied to medical devices."[95] Judge Robreno agreed with the Superior Court's conclusion two years ago in *Rosenberg v. C.R. Bard, Inc.* Judge Robreno first looked to the language of comment k, which "specifically contemplates its application to prescription products such as 'drugs, vaccines, and the like, many of which . . . cannot be sold except to physicians, or under the prescription of a physician.'"[96] Based on this language, he concluded, "comment k's plain language appears to include prescription medical devices because 'prescription' medical devices, by definition, are products that require a physician's prescription."[97] He held, "[f]or the purposes of comment k, no meaningful distinction can be drawn between prescription drugs and prescription medical devices."[98] He further supported his analysis by citing *Creazzo* and explaining "every federal district court to confront this issue has predicted that the Pennsylvania Supreme Court would extend comment k's application to prescription medical devices."[99]

Our colleagues have decided the other way as well. Judge Baylson disagreed with the reasoning in *Creazzo* last year and predicted the Pennsylvania Supreme Court would allow strict liability claims involving medical devices to proceed past the motion to dismiss stage.[100] Judge Baylson reasoned, "[f]ollowing *Creazzo*, a few Pennsylvania Supreme Court decisions cautioned, both in general terms and with specific reference to *Hahn* and comment k, against

lightly altering the common law of products liability."[101] Judge Baylson cited the Pennsylvania Supreme Court's decisions in *Tincher v. Omega Flex, Inc.*[102] and *Lance v. Wyeth*[103]. In *Tincher*, the court cautioned against carving out exceptions to strict liability for categories and types of products.[104] In *Lance*, the court advised courts not to readily expand *Hahn*, advising "[*Hahn*] applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k . . . [T]he truncated analysis in *Hahn* offers a poor foundation for extrapolation."[105] Judge Baylson reasoned, "these decisions . . . vitiate *Creazzo's* reliability as evidence of how [the Supreme Court of Pennsylvania] would decide whether comment k covers medical devices."[106]

Guided by our own review of *Hahn* and comment k as well as Judge Robreno's reasoning in *Rosenberg* and the Pennsylvania Superior Court's warning in *Creazzo*, we predict the Pennsylvania Supreme Court would extend comment k to preclude liability for prescription medical devices. In explaining what constitutes an "unavoidably unsafe product," the drafters of the Restatement referred to "drugs, vaccines, *and the like* . . . which . . . cannot legally be sold except to physicians or under the prescription of a physician."[107] The "and the like" language extends the scope beyond drugs and vaccines to similar products, like medical devices, which "cannot be legally sold except to physicians or under the prescription of a physician."[108] Like Judge Robreno and the Pennsylvania Superior Court, we do not see a basis for distinguishing between prescription medical devices and prescription medical drugs for the purposes of applying comment k. But we also heed Judge Baylson's warning in *Gross* not to extend *Hahn* too far, and for the reasons discussed below, we will not apply comment k and *Hahn* to manufacturing defects.

iii. We predict the Pennsylvania Supreme Court would not extend comment k and *Hahn* to preclude strict liability for manufacturing defects.

Although we find comment k extends to prescription medical devices, we predict the Pennsylvania Supreme Court would not extend it to manufacturing defect claims.

Courts are split on whether comment k applies to manufacturing defects in prescription medical products. In *Smith v. Howmedica Osteonics Corp.*, Judge Beetlestone predicted, "the Pennsylvania Supreme Court would not bar strict liability claims asserting a manufacturing defect against manufacturers under Comment k."[109] She reasoned, "Comment k protection is explicitly conditioned on the product being 'properly prepared' and 'accompanied by proper directions and warning.'"[110] She continued, "[o]n its face, this language might seem to preserve strict liability for claims asserting a manufacturing defect and a failure-to-warn defect, even where Comment k applies," but she recognized *Hahn* eliminated strict liability for failure-to-warn claims.[111]

Analyzing a split in this District regarding whether comment k applies to manufacturing defects, Judge Beetlestone held, "[t]hose opinions allowing a manufacturing defect claim to proceed in strict liability under Comment k have the better analysis" because "*Hahn's* rationale is not obviously transferrable to the manufacturing defect context because it relied primarily on an interpretation of Comment j to Section 402A, which defines proper 'directions and warnings.'"[112] As Judge Baylson noted in *Gross*, Judge Beetlestone explained expanding *Hahn* beyond the facts on which it arose "seems increasingly questionable as the Pennsylvania Supreme Court in *Lance* went out of its way to criticize *Hahn* and its progeny, noting that 'the truncated analysis in the *Hahn* line offers a poor foundation for extrapolation.'"[113]

Judge Robreno reached a different conclusion in *Rosenberg*, predicting "the Pennsylvania Supreme Court would extend comment k's mantle of protection both to prescription drugs and prescription medical devices and that, under this view, comment k precludes strict liability claims based on a manufacturing defect."[114] But he noted, "there is 'substantial ground for difference of opinion' as to whether . . . there remains a carve-out for strict liability manufacturing claims for prescription medical devices," counting "at least nine district courts within the Third Circuit that have allowed [manufacturing defect for prescription medical devices] strict liability claim[s] to proceed and at least five district courts that have specifically explained that comment k bars all three types of strict liability claims." [115]

Although we find, as Judge Robreno did, "there is substantial ground for difference of opinion,"[116] we agree with Judge Beetlestone the Pennsylvania Supreme Court would not expand *Hahn* to prohibit strict liability claims for manufacturing defects under comment k. We agree with Judge Beetlestone the "properly prepared" language appears to carve out manufacturing defects from liability. We further agree the Pennsylvania Supreme Court's warning in *Lance* not to expand *Hahn* too quickly suggests the Pennsylvania Supreme Court would not extend *Hahn* to manufacturing defects.

iv. Ms. Drumheller fails to plead a manufacturing defect claim.

Although Pennsylvania law allows Ms. Drumheller's strict liability manufacturing claim, we find Ms. Drumheller fails to plead a manufacturing defect because, as discussed above, she fails to plead a deviation from a suitable design. We dismiss the manufacturing defect claim without prejudice.

D. We dismiss Ms. Drumheller's breach of implied warranty claims as time-barred and her express warranty claims as inadequately pled.

Ethicon moves to dismiss Ms. Drumheller's breach of warranty claims, arguing: (1) Pennsylvania's four-year statute of limitations bars her claims; (2) Ms. Drumheller does not adequately plead her claims; and (3) Pennsylvania's bar on strict liability for prescription medical devices extends to claims for breach of implied warranty. Ms. Drumheller argues her claims are "tolled due to Defendants' fraudulent concealment and waiver, and [are] otherwise tolled due to equitable estoppel and the discovery rule."[117] She further argues her claims are adequately pled, and comment k does not extend to breach of implied warranty claims.[118]

We agree with Ethicon Ms. Drumheller's breach of implied warranty claims are time-barred, but we cannot determine from the allegations whether her breach of express warranty claims is time-barred. We find Ms. Drumheller fails to plead a breach of express warranty. We do not address whether Pennsylvania allows breach of implied warranty claims for injuries regarding from prescription medical drugs or devices.

i. Ms. Drumheller's breach of implied warranty claims are time-barred, but we have insufficient information to determine whether her breach of express warranty claims are time-barred.

Ethicon argues Ms. Drumheller's breach of warranty claims are time-barred. Ms. Drumheller argues we should toll the statute of limitations under the discovery rule and because Ethicon "fraudulent concealed" the dangers of pelvic mesh. We find Ms. Drumheller's breach of implied warranty claims time-barred, but we have insufficient information to reach a conclusion on whether her breach of express warranties are time-barred.

Under Pennsylvania law, breach of warranty claims "must be commenced within four years after the cause of action has accrued."[119] "It is well-settled that breach of warranty claims are not subject to the discovery rule."[120] "A cause of action accrues when the breach occurs,

regardless of the aggrieved party's lack of knowledge of the breach."[121] "A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered."[122] In cases involving the implantation of a medical device, a breach of warranty cause of action accrues on the date the device is implanted.

But there is one significant exception before us today: the limitations period may expand if the warranty "explicitly extends to future performance."[123] To determine whether Ms. Drumheller's breach of warranty claims are timely, we must determine whether her warranties explicitly extended to future performance.

Judge Gibson analyzed the timeliness of breach of warranty claims involving a surgically implanted medical device in *McPhee v. DuPuy Orthopedics, Inc.*[124] Judge Gibson first assessed the breach of implied warranties. He explained, "[w]hether an implied warranty can be 'explicitly' extended forward has not been squarely decided by the Supreme Court of Pennsylvania," but "[t]he Supreme Court of Pennsylvania's most recent expositions on this issue suggest that implied warranties cannot be so extended."[125] He thus held, "Plaintiffs' implied warranty claims are not timely because the statute of limitations expired [nine years before plaintiff brought suit]—four years after the cause of action accrued . . . when the device was implanted in [the patient]."[126]

Judge Gibson then addressed the breach of express warranty claims. He found it "impossible to determine from the face of the Complaint whether the express warranties allegedly made by Defendant were explicitly extended forward" because although the plaintiff alleged "Defendant expressly warranted that the device was safe, effective, durable, free from

defects, merchantable and proper for its intended use" the plaintiff did not identify specific representations made by Defendant giving rise to these express warranties.[127] He reasoned, "[a]n analysis of whether a 'warranty 'explicitly' extends to future performance must focus on the language of the warranty'" and "[w]ithout an opportunity to review the statements that Plaintiff alleges gives rise to the express warranties, the Court cannot determine whether the alleged express warranties were extended forward, which in turn prevents this Court from determining the date on which the cause of action accrued."[128] He thus could not "calculate the expiration of the four-year statute of limitations period."[129]

Ms. Drumheller underwent her surgical mesh implantation over ten years ago, well outside the four-year statute of limitations. Ms. Drumheller alleges Ethicon warranted the products as "safe and effective" and "safer and more effective that [sic] other alternative procedures and devices."[130] Ms. Drumheller alleges Ethicon express warranties include the pelvic mesh product is "safe and effective", "does not contract or shrink", "does not degrade", and may "only cause transient or temporary injuries".[131] She further alleges Ethicon warranted the pelvic mesh product "will permanently cure or alleviate" her stress urinary incontinence and would not need to be partially removed.[132]

We find, as Judge Gibson did, Ms. Drumheller's breach of implied warranty claims are time-barred. We agree with Judge Gibson's conclusion an implied warranty cannot be "explicitly extended to future performance" and thus Ms. Drumheller's breach of implied warranty claims expired in 2013 and 2014 – four years after her implantation surgeries.

Ms. Drumheller's breach of express warranty claim is a different story. Unlike the claims reviewed by Judge Gibson in *McPhee*, which alleged the defendant made representations about the general safety and efficacy of the product, Ms. Drumheller alleges Ethicon expressly

warranted the pelvic mesh "will permanently cure or alleviate" her stress urinary incontinence and would not need to be partially removed.[133] She also alleges Ethicon warranted the product would not shrink, degrade, or deform – thereby assuring the product's performance over time. Taking these allegations as true, as we must at this stage, we find it plausible the representation about the continued safety and efficacy of the permanent implant's performance extended to future performance.

ii. Ms. Drumheller fails to plead a claim for breach of express warranty.

We next assess whether Ms. Drumheller adequately states a breach of an express warranty claim under Federal Rule of Civil Procedure 8 and *Twombly*. We find she does not state a claim for breach of express warranty.

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise."[134] In breach of express warranty cases, courts in our Circuit applying Pennsylvania law generally require a plaintiff to identify a specific affirmative statement to withstand a motion to dismiss.

In *Runner*, Judge Dalzell dismissed a plaintiff's breach of express warranty claims because the plaintiff "failed to identify any affirmative statements by either defendant."[135] Judge Dalzell reasoned the plaintiff, by not identifying specific statements by the defendant, "failed to identify anything he relied on that made him decide on the purchase and the use of the mesh product."[136]

Judge Gibson in *McPhee* also dismissed the plaintiff's breach of express warranty claims because the plaintiff "fail[ed] to identify any affirmation of fact or promise giving rise to the[] alleged [express] warranties."[137] In *McPhee*, the plaintiff alleged the defendant "expressly

warranted in its written literature, advertisements and representations of its representatives and its agents that its [prescription medical devices] were safe, effective, fit and proper for the use for which they were intended."[138] He explained, "[b]ecause Plaintiff cannot allege that any particular affirmation of fact or promise became 'part of the basis of the bargain' without alleging an affirmation of fact or promise, . . . Plaintiffs' complaint fails to allege facts sufficient to demonstrate a plausible claim for breach of express warranties under Pennsylvania law."[139]

In *McLaughlin v. Bayer*, Judge Padova dismissed a breach of express warranty claim against a manufacturer of a birth control device.[140] In *McLaughlin*, the plaintiffs quoted alleged warranties found in advertisements, websites, and brochures.[141] But Judge Padova noted the plaintiffs "fail[ed] to allege any circumstances under which each Plaintiff read or saw each particular warranty, or how that warranty came to be the basis of each Plaintiff[s]' bargain with [the device manufacturer]."[142] Instead, the plaintiffs pled "wholly conclusory allegations that warranties were 'specifically negotiated and expressly communicated to Plaintiff[s] in such a manner that Plaintiff[s] understood and accepted them,' and that the affirmations of fact or promises in the warranties 'created a basis of the bargain' between Plaintiffs and [the device manufacturer]."[143]

Judge Padova then identified several deficiencies with the allegations. He noted, "[w]hile the Complaint alleges that certain warranties appeared in advertisements and marketing, it does not allege whether the advertisements appeared in magazines, newspapers or other publications, on posters, on the internet, or on the television."[144] Nor did the plaintiffs identify "the titles of, or any other identifying information for, the alleged brochures."[145] He also noted the plaintiffs failed "to allege how or when each Plaintiff encountered each warranty beyond alleging the general time frame of 'prior to implantation,' which covers a period of many years."[146] Judge

Padova thus held the plaintiffs failed to "allege facts that give rise to a reasonable inference that each alleged warranty was an affirmation of fact or promise that formed the 'basis of the bargain' between [the device manufacturer] and each Plaintiff."[147]

Like the plaintiffs in *Runner, McPhee*, and *McLaughlin*, Ms. Drumheller alleges Ethicon generally stated the pelvic mesh product is "safe and effective." Unlike the plaintiffs in *McLaughlin*, who provided quotes of express language from a variety of advertisements and brochures, Ms. Drumheller does not provide the specific warranties on which she allegedly relied. She instead paraphrases several alleged express warranties, alleging Ethicon warranted the product: "does not contract or shrink", "does not degrade", and may "only cause transient or temporary injuries".[148] She further alleges Ethicon warranted the pelvic mesh product "will permanently cure or alleviate" her stress urinary incontinence and would not need to be partially removed.[149] Like in *McLaughlin*, she does not allege the specific materials containing these warranties, nor does she allege how she became aware of these materials. Like Judge Padova, we find her allegations insufficient to plead Ethicon made express warranties which became the basis of the bargain between the two parties.

E. We dismiss Ms. Drumheller's fraud claims as Pennsylvania law does not allow fraud claims predicated on a failure-to-warn theory.

Ethicon moves to dismiss Ms. Drumheller's fraud and misrepresentation claims which it characterizes are based on the theory Ethicon failed to disclose material information about the mesh products' safety, and under Pennsylvania law, "negligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription drug manufacturer when the claim is essentially that the drug company knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product's safety."[150] Ethicon further argues Ms. Drumheller fails to plead her fraud and misrepresentation claims with

particularity. We find Ms. Drumheller's fraud claims are barred by Pennsylvania's limitation on failure-to-warn claims. We do not address Ethicon's other grounds for dismissal of the fraud claims.

"[N]egligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription [device] manufacturer when the claim is essentially that the drug company knew of the dangers associated with the product but concealed that information while fraudulently misrepresenting the product's safety."[151] Courts in this District routinely dismiss fraud claims rooted in a failure to warn theory.

For example, in *Runner*, the plaintiff asserted causes of action for negligent misrepresentation and fraudulent concealment alleging the defendants concealed the dangers associated with pelvic mesh.[152] Defendants moved to dismiss his fraud and misrepresentation claims, arguing the claims were "tantamount to failure-to-warn claims."[153] Judge Dalzell agreed with defendants, explaining, "Pennsylvania law holds that fraudulent misrepresentation claims in medical injury suits are rooted in failure to warn."[154] Judge Dalzell cited *Kline v. Pfizer Inc*.[155] In *Kline*, the plaintiff brought a products liability suit against a drug manufacturer, asserting fraud and misrepresentation claims in addition to failure-to-warn claims.[156] Judge Kelly dismissed the fraud and misrepresentation claims, explaining "[w]hile [plaintiff] attempts to characterize these claims as 'so much more than a failure to warn claim' . . . these claims do, in fact, assert liability against [defendant] for failure to warn."[157] He reasoned, "[t]he very basis of these claims is that [defendant] knew of the dangers associated with [the drug] but fraudulently concealed this knowledge and fraudulently misrepresented that the drug was safe by failing to warn of its dangers."[158] He concluded, "[t]hus, the very crux of these claims rests on a failure to warn theory of liability."[159]

Like in *Runner* and *Kline*, Ms. Drumheller's fraud and misrepresentation claims sound in failure-to-warn. As Ms. Drumheller's sole avenue for recovery for these types of claims is negligent failure to warn, we dismiss the fraud claims without prejudice.

F. We do not dismiss Ms. Drumheller's negligent infliction of emotional distress claim.

Ethicon argues Ms. Drumheller fails to state a claim for negligent infliction of emotional distress because she fails to adequately plead emotional harm. Ms. Drumheller argues her allegations are sufficient. We agree with Ms. Drumheller at this early stage.

"Under Pennsylvania law, a [negligent infliction of emotional distress] claim arises only when (1) the defendant had a contractual or fiduciary duty toward the plaintiff; (2) the plaintiff was subjected to a physical impact; (3) the plaintiff was in a zone of danger and reasonably feared impending physical injury; or (4) the plaintiff observed a tortious injury to a close relative."[160] The plaintiff must also allege "some physical harm" resulting from her emotional distress. The "physical harm" cannot be temporary or transitory in nature but must be repeated or ongoing.[161]

In *Runner*, Judge Dalzell dismissed a plaintiff's negligent infliction of emotional distress claims, finding the plaintiff failed to adequately allege physical emotional harm. Judge Dalzell explained, "[i]t has long been the rule in Pennsylvania that a plaintiff must allege some physical harm."[162] He elaborated, "a plaintiff must allege *some* emotional disturbance beyond 'transitory nonrecurring physical phenomena, harmless in themselves' and 'tantamount to physical harm that 'may be classified by the courts as illness notwithstanding their mental character.'"[163] By way of example, Judge Dalzell cited to the Pennsylvania Supreme Court's ruling in *Toney v. Chester County Hospital*, where it found the plaintiff adequately alleged emotional harm by alleging her emotional shock manifested in "nausea, headaches, insomnia, depression,

nightmares, flashbacks, repeated hysterical attacks, stress and anxiety."[164] The plaintiff in *Runner*, by contrast, failed to allege emotional disturbance beyond the bald assertion he "suffered injuries."[165] Judge Dalzell thus found he failed to plead an essential element of negligent infliction of emotional distress.[166]

Ms. Drumheller pleads she "sustained physical injuries . . . that were caused by psychological trauma (stress, anxiety, sadness, anger etc.)" and this "emotional distress was and is so severe that no reasonable person could be expected to endure it."[167] She alleges her emotional distress was "medically diagnosable."[168]

We find Ms. Drumheller narrowly pleads negligent infliction of emotional distress. Unlike the plaintiff in *Runner*, who alleged he suffered unspecified "injuries," Ms. Drumheller alleges she has long suffered severe, "medically diagnosable" stress and anxiety as a result of her pelvic mesh implantation. She alleges this stress and anxiety continues to this day. We find these allegations sufficient at this stage to state a claim for negligent infliction of emotional distress.

G. We dismiss Ms. Drumheller's unjust enrichment claim.

Ms. Drumheller seeks unjust enrichment alleging she did "not receive[] the safe and effective medical devices for which she paid."[169] Ethicon argues Ms. Drumheller fails to plead an unjust enrichment claim.[170] We agree Ms. Drumheller does not state a claim for unjust enrichment.

Under Pennsylvania law, "unjust enrichment claims . . . fall into one of two categories: (1) a quasi-contract theory of liability, where the unjust enrichment claim is brought as an alternative to a breach of contract claim; or (2) a 'companion' theory of liability, where the unjust enrichment claim is a companion to a tort claim and seeks to divest the defendant of a

benefit obtained by committing the tort."[171] Under the second theory, "the unjust enrichment seeks to recover a benefit the defendant gained by committing the tort."[172] Therefore, "an unjust enrichment claim is essentially another way of stating a traditional tort claim,"[173] and "where the unjust enrichment claim rests on the same improper conduct as the underlying tort claim, the unjust enrichment claim will rise or fall with the underlying claim."[174]

In products liability cases, courts in this Circuit applying Pennsylvania law dismiss unjust enrichment claims where the plaintiff received and used the product at issue. For example in *Mazur v. Milo's Kitchen, LLC*, Judge Bissoon dismissed an unjust enrichment claim where the plaintiff alleged her dog suffered kidney failure after eating the defendant's chicken jerky.[175] Judge Bissoon reasoned, "while [the plaintiff] was dissatisfied with the chicken jerky treats, she nevertheless purchased, received, and used the product."[176] She concluded, "[i]t therefore cannot be said that the benefit bestowed on in the form of a profit from the sale was 'wrongly secured.'"[177] Judge Bissoon cited Judge Dubois's analysis in *Tatum v. Takeda Pharmaceuticals North America, Inc*.[178] In *Takeda*, the plaintiff brought a products liability suit against a pharmaceutical company, alleging the defendant's drug weakened his bones.[179] Judge DuBois dismissed the unjust enrichment claim holding "there is no allegation that defendants refused to provide a services or goods after [the plaintiff] provided defendants with a benefit."[180]

As in *Milo* and *Takeda*, Ms. Drumheller does not allege she paid for, but did not receive the product at issue; rather she alleges her dissatisfaction with the product. She does not state an unjust enrichment claim.

H. We dismiss Ms. Drumheller's claim for "punitive damages."

"A request for punitive damages does not constitute a cause of action in an[d] of itself[;] [r]ather a request for damages is merely incidental to a cause of action."[181] We dismiss her

standalone punitive damages claim without prejudice to her ability to seek punitive damages as a remedy for her claims subject to discovery and trial.

III. Conclusion

We grant in part and deny in part Ethicon's motion to dismiss.

We grant Ethicon's motion to dismiss Ms. Drumheller's negligence claim in part and deny in part. We dismiss the negligence claim to the extent her claim is predicated on a manufacturing defect theory, but we will allow her to proceed on her theories of negligent design and negligent failure to warn. We dismiss her design defect and failure to warn claims to the extent Ms. Drumheller seeks to impose strict liability for the alleged design and failure-to-warn defect because we predict the Pennsylvania Supreme Court would foreclose strict liability claims for failure-to-warn and design defects. But we will allow her to proceed on her design defect and failure to warn defect claims under a negligence theory. She may also proceed on her negligent infliction of emotional distress claims.

We dismiss the remaining claims. We dismiss her manufacturing defect claim because Ms. Drumheller fails to plead a deviation from a suitable design. We dismiss Ms. Drumheller's gross negligence claim because gross negligence is not an independent cause of action under Pennsylvania law. We dismiss Ms. Drumheller's common law fraud, constructive fraud, negligent misrepresentation, and fraudulent concealment claims because Ms. Drumheller may not recover under a fraud or misrepresentation theory for a medical device manufacturer's failure to warn. We dismiss Ms. Drumheller's breach of implied warranty claim as time barred. We dismiss her breach of express warranty claim because she fails to plead a specific affirmation of fact or promise which became the basis of the bargain. We dismiss Ms. Drumheller's unjust enrichment claim because she fails to state a claim for unjust enrichment. We dismiss Ms.

Drumheller's punitive damages claim because punitive damages are a remedy, not a cause of action, but we do not foreclose Ms. Drumheller from seeking punitive damages as a remedy.

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[1] First amended Complaint, ECF Doc. No. 16 ¶¶ 1-3.

[2] *Id.* ¶¶ 5-6. Johnson & Johnson owns Ethicon, Inc. We refer to both Defendants collectively as "Ethicon."

[3] *Id.* ¶ 4.

[4] *Id.* ¶ 11.

[5] *Id.*

[6] *Id.*

[7] *Id.* ¶ 19.

[8] *Id.* ¶ 13.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.* ¶ 18.

[13] *Id.* ¶ 15.

[14] *Id.*

[15] *Id.*

[16] *Id.* ¶ 16.

[17] *Id.* ¶ 17.

[18] *Id.*

[19] *Id.* ¶ 126.

[20] *Id.*

[21] *Id.* ¶ 25; Federal Food, Drug and Cosmetic Act, § 510(k), as amended, 21 U.S.C. 360(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed before May 28, 1976.

[22] ECF Doc. No. 16 ¶¶ 19, 25.

[23] *Id.* ¶ 41.

[24] *Id.* ¶ 26.

[25] *Id.* ¶ 27.

[26] *Id.* ¶ 28.

[27] *Id.*

[28] *Id.* ¶ 30.

[29] *Id.* ¶ 31.

[30] *Id.* ¶ 33.

[31] *Id.* ¶ 34.

[32] *Id.*

[33] *Id.* ¶ 35.

[34] *Id.* ¶ 36.

[35] *Id.* ¶ 40.

[36] *Id.*

[37] *Id.* ¶ 12.

[38] *Id.* ¶ 14.

[39] *Id.*

[40] *Id.* ¶ 61.

[41] *Id.* ¶ 21.

[42] *Id.* ¶ 22.

[43] *Id.*

[44] *Id.* ¶ 23.

[45] When considering a motion to dismiss "[w]e accept as true all allegations in the plaintiff's complaint as well as all reasonable inferences that can be drawn from them, and we construe them in a light most favorable to the non-movant." *Tatis v. Allied Interstate, LLC*, 882 F.3d 422, 426 (3d Cir. 2018) (quoting *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010)). To survive dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Our Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal*, 556 U.S. at 675, 679).

[46] ECF Doc. No. 20-1 at 5.

[47] *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017) (quoting *Weiland v. Palm Beach County Sheriff's Office*, 792 F.3d 1313, 1321 (11th Cir. 2015)).

[48] *Id.* (quoting *Weiland*, 792 F.3d at 1321).

[49] *Pension Trust Fund for Operating Eng'rs v. Mortg. Asset Securitization Transactions, Inc.*, 730 F.3d 263, 271 (3d Cir. 2013).

[50] *Id.* (quoting *Tregenza v. Great Am. Commc'ns Co.*, 12 F.3d 717 (7th Cir. 1993)).

[51] *Id.*

[52] Ethicon moves to dismiss Ms. Drumheller's gross negligence claims, arguing the gross negligence claim fails for the same reason the negligence claim fails. As Ms. Drumheller pointed out "Defendants failed to argue that Plaintiff's gross negligence claim is not an independent cognizable claim in Pennsylvania," and she concedes "this independent claim . . . "should be dismissed." ECF Doc. No. 23 at 12. But she also argues "the relevant allegations . . . [should] not fall away along with that dismissed claims" because these allegations support her prayer for punitive damages. *Id.* (citing *Veolia Energy Philadelphia, Inc. v. Flowserve US, Inc.*, 2019 WL 1966476, at *2 (E.D. Pa. Apr. 30, 2019)). We appreciate Ms. Drumheller's candor on the viability of her gross negligence claim, and we dismiss her gross negligence claim with

prejudice. In dismissing the claim, we will not strike her allegations of gross negligence and will not preclude her from seeking punitive damages at this early stage.

[53] ECF Doc. No. 20 at 6-7.

[54] ECF Doc. No. 16 ¶¶2-3.

[55] *Id.* ¶ 15.

[56] *Id.* ¶16.

[57] *Id.* ¶17.

[58] ECF Doc. No. 27-1.

[59] ECF Doc. No. 23 at 9.

[60] *Terroll v. Davol, Inc.*, No. 13-5074, 2014 WL 3746532, at * 7 (E.D. Pa. Jul. 30, 2014).

[61] *Id.* (citations and quotation marks omitted).

[62] *Id.* (citations and quotation marks omitted).

[63] *Id.* (citations and quotation marks omitted).

[64] *Id.* ¶ 124.

[65] *Id.* ¶ 129.

[66] *Id.* ¶ 128.

[67] *Terroll*, 2014 WL 3746532, at * 7.

[68] *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. Ct. 2010) (citing *Simon v. Wyeth Pharms., Inc*., 989 A.2d 356, 368 (Pa.Super.Ct. 2009)).

[69] *Id.* (citing *Taurino v. Ellen*, 579 A.2d 925, 927 (1990)).

[70] *Id.*

[71] *Id.*

[72] *Id.* (citing *Simon*, 989 A.2d at 368).

[73] *Id.*(citing *Whitner v. Von Hintz*, 263 A.2d 889, 893-94 (Pa. 1970)).

[74] *Id.*

[75] 108 F. Supp. 3d 261, 271 (E.D. Pa. 2015).

[76] *Id.* at 271-72.

[77] *Id.* at 272.

[78] ECF Doc. No. 16 ¶ 136.

[79] *Id.* ¶ 139-40.

[80] *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 576 (E.D. Pa. 2019).

[81] *Id.*

[82] *Id.*

[83] *Id.*

[84] Restatement (Second) of Torts § 402A cmt. k.

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] 673 A.2d 888, 890 (Pa. 1996).

[92] *Id.* at 891.

[93] *Id.*

[94] 4 A.3d 160, 165 (Pa. Super. Ct. 2010), *appeal granted on other grounds,* 15 A.3d 429 (Pa. 2011).

[95] 903 A.2d 24, 31 (Pa. Super. Ct. 2006).

[96] *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 577 (E.D. Pa. 2019).

[97] *Id.*

[98] *Id.*

[99] *Id.* citing (*Buck v. Endo Pharm*., Inc., No. 19-837, 2019 WL 1900475, at *1 (E.D. Pa. Apr. 29, 2019); *Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004); *Murray v. Synthes* (U.S.A.), Inc., No. 95-7796, 1999 WL 672937, at *7–8 (E.D. Pa. Aug. 23, 1999); *Burton v. Danek Med., Inc*., No. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999); *Taylor v. Danek Med., Inc.*, No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998).

[100] *Gross v. Coloplast*, 434 F. Supp. 3d 245 (E.D. Pa. 2020).

[101] *Id.* at 250.

[102] 104 A.3d 328 (Pa. 2014).

[103] 85 A.3d 434 (Pa. 2014).

[104] 104 A.3d at 409 (“In either case, this jurisdiction's experience with the repercussions of attempting to articulate specific principles of liability of broad application in implementing the strict liability cause of action make us reticent to go far beyond the necessities of an individual case and embrace a broad new approach premised upon what may prove to be procrustean categorical restrictions.”).

[105] 85 A.3d at 453.

[106] *Gross*, 434 F. Supp. 3d at 251.

[107] Restatement (Second) of Torts § 402A cmt. k.(italics supplied).

[108] *Id.*

[109] 251 F. Supp. 3d 844, 847 (E.D. Pa. 2017).

[110] *Id.*

[111] *Id.*

[112] *Id.*

[113] *Id.* (citing *Lance*, 85 A.3d at 452 n.21).

[114] 387 F. Supp. 3d at581.

[115] *Id.*

[116] *Id.*

[117] ECF Doc. No. 23 at 17.

[118] *Id.* at 18.

[119] 13 Pa. Cons. Stat. Ann. § 2725.

[120] *Speicher v. Dalkon Shield Claimants Trust*, 943 F. Supp. 554, 558 (E.D. Pa. 1996).

[121] *Id.*

[122] *Id.*

[123] *See McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 463 (W.D. Pa. 2012).

[124] *Id.* at 463.

[125] *Id.*

[126] *Id.*

[127] *Id.* at 464.

[128] *Id.* at 464-65.

[129] *Id.* at 465.

[130] ECF Doc. No. 16 ¶ 200.

[131] *Id.* ¶ 199.

[132] *Id.* ¶ 189.

[133] ECF Doc. No. 16 ¶ 189.

[134] 13 Pa. Const. Stat. Ann. § 2313(a).

[135] 108 F. Supp. 3d at 266.

[136] *Id.*

[137] *McPhee*, 989 F. Supp. 2d at 466.

[138] *Id.* at 467.

[139] *Id.* at 466.

[140] *McLaughlin v. Bayer Corp.*, 172 F. Supp.3d 804 (E.D. Pa. 2016).

[141] *Id.* at 823.

[142] *Id.*

[143] *Id.* at 824.

[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] *Id.* ¶ 199.

[149] *Id.* ¶ 189.

[150] ECF Doc. No. 20-1 at 14.

[151] *Runner*, 108 F. Supp. 3d at 268.

[152] *Id.*

[153] *Id.*

[154] *Id.*

[155] *Kline v. Pfizer*, No. 08-3238, 2009 WL 32477 (E.D. Pa. Jan. 6, 2009).

[156] *Id.*

[157] *Id.* at *4.

[158] *Id.*

[159] *Id.*

[160] *Runner*, 108 F. Supp. 3d at 272.

[161] *Id.*; *see also Armstrong v. Paoli Mem. Hosp.*, 633 A.2d 605, 609 (Pa. Super. Ct. 1993).

[162] *Id.* at 273.

[163] *Id.* (citing *Toney v. Chester Cnty. Hosp.,* 961 A.2d 192, 197–98 (Pa.Super.Ct.2008)).

[164] *Id.* (citing *Toney*, 961 A.2d at 85).

[165] *Id.* at 273.

[166] *Id.*

[167] *Id.*¶¶ 274-76.

[168] *Id.* ¶ 276.

[169] ECF Doc. No. 16 ¶ 323.

[170] ECF Doc. No. 20-1 at 14-15.

[171] *Symphony FS Ltd. v. Thompson,* No. 18-3904, 2018 WL 6715894, at *9 (E.D. Pa. Dec. 20, 2018).

[172] *Id.*

[173] *Id*. at *10.

[174] *Whitaker v. Herr Foods, Inc*., 198 F. Supp. 3d 476, 493 (E.D. Pa. 2016).

[175] No. 12-1011, 2013 WL 345203, at *10 (W.D. Pa. June 25, 2013).

[176] *Id.*

[177] *Id.*

[178] No. 12-1114, 2012 WL 5182895 (E.D. Pa. Oct. 9, 2012).

[179] *Id.*

[180] *Id.* at *5.

[181] *Nix v. Temple Univ. of Com. Sys. of Higher Educ.*, 596 A.2d. 1132, 1138 (Pa. 1991).